

OKP 94 4420

**IR EHF Therapy apparatus
“TRIOMED”**

Model “TRIOMED-KOMPACT 1-8”

PASPORT Operation Manual

TGKB 941.526.002 RE

St-Petersburg 2011

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INTRODUCTION

Operation Manual (RE) is intended for teaching users correct use of IR and EHF therapy apparatus "TRIOMED" model "TRIOMED-KOMPACT 1-8" (further referred to as apparatus).

In order to avoid problems while using the apparatus read attentively the manual!

While using it is necessary to use additionally Instructions on the application of IR EHF Therapy apparatus TGKB 941.526.002 IP.

ATTENTION!

EHF - action should be avoided in case of:

- Uncertain diagnosis;
- Individual intolerance of the action;
- Feverish states of obscure etiology;
- Presence on the patient of implanted devices with autonomous power source (in the area of the device).

Patients who are oversensitive to EHF radiation and have counter-indications mentioned in the Use Instructions before applying the apparatus have to consult their doctor.

It is forbidden to store the apparatus in places accessible to children and pets.

1. DESCRIPTION AND OPERATION

1.1. Function

1.1.1. IR and EHF therapy apparatus "TRIOMED" model "TRIOMED-KOMPACT 1-8" is a portable physiotherapy and reflexology medical apparatus designed for treatment and prophylaxis of different pathology states by action of low-intensity electromagnetic radiation of extremely high-frequency (EHF) and infrared (IR) ranges on human skin sections.

1.1.2. Recommendations on the selection of method and biologically active zones for EHF or IR action are mentioned in the Use Instructions.

1.1.3. Apparatus can be used by therapeutic, therapeutic and prophylactic establishments of the wide spectrum and individually under medical supervision in hospitals, medical centers and at home.

1.1.4. Special training of personnel for using the apparatus is not required.

1.2. Technical characteristics

1.2.1. The apparatus complies with GOST R 50444, TU 9444-018-61005106-2010 and with design documentation set (KD) TGKB 941.526.002. requirements.

1.2.2. According to the mode of application the apparatus belongs to articles of repeated cyclic use.

1.2.3. Apparatus is made to resist mechanical action in accordance with group 2 of GOST R 50444 in the climatic conditions UKHL 4.2 according to GOST 15150.

On safety the apparatus complies with GOST R 50267.0 requirements and is executed as an article with build-in safe power source, type B.

On potential risk of use the apparatus belongs to class 2a according to GOST R 51609.

1.2.4. Purchased spare parts and components conform with the requirements of the normative documents, duly approved and certificates by the producers.

1.2.5. Apparatus is made as a monoblock and consists of generation unit and IR oscillator, source of power, 4 built-in light-emitting diodes and a buzzer.

Electromagnetic radiations EHF "BioTrEM" generator № 1 produced in compliance with TU 6349-010-61005106-2010 and a set of design documentation (KD) TGKB 435.729.004.

1.2.6. Apparatus operates from the internal power source, one element CR 2032 with the nominal DC voltage 3,0 V.

1.2.7. The consumption current – A - not more than 0,02, consumed power, mVA, not more than 100.

1.2.8. Dimensions, mm, not more than - 75×45×13.

1.2.9. Mass, kg, not more than - 0,1.

1.2.10. Apparatus ensures output characteristics: carrier frequency - 40 ÷ 43 GHz, wavelength - 7,5 ÷ 6,98 mm, carrier modulation frequency - 1÷100 ± of 0,5 Hz, exposure time - 1÷1800 s, average power of EHF radiation or IR flow capacity - 0,001÷0,01 mW.

1.2.11. Apparatus provides normal standard operation during 1000 hours with declared characteristics.

1.2.13. Apparatus has built-in timer which ensures switching-off after ending the procedure.

1.2.14. Apparatus has light and sound indication of the following states:

- switching of generation;
- discharge of batteries;
- malfunction of apparatus.

1.2.15. Apparatus's body is made of plastics ABC HI-121, manufacturer "LG Chem, LTD" (Korea) or other material allowed for application on non-toxic index.

1.2.16. Outer surfaces of parts of the apparatus are resistant to disinfection according to MU 287-113 by 3% solution of hydrogen peroxide in conformity with GOST 177 with addition of 0,5% of cleaning agent according to GOST 25644.

1.2.17. Apparatus while operating is resistant to climatic actions of parameters according to GOST 15150 for complying with UKHL 4.2: nominal values of temperature above +35 °C, below +10 °C; relative humidity 80% at 25 °C.

1.2.18. Apparatus in operation is resistant to mechanical actions with parameters according to GOST R 50444 for group of articles 2: vibration in the range of frequencies 10-55 Hz at displacement amplitude of 0,15 mm.

1.2.19. Apparatus in the transport packaging is resistant to the climatic actions with parameters according to GOST 15150 for conditions for storage 5,6.

1.2.20. Apparatus in the transport packaging is resistant to mechanical actions with parameters according to GOST R 50444 for transport.

1.2.21. Average operating time of apparatus to the failure - not less than 1500 hours. Nonconformity to the declared characteristics of apparatus is the criterion of non working state.

1.2.22. Average life of apparatus before disposal is not less than 5 years. Criterion of the limit condition of apparatus is non-operating state when its restoration technically or economically is not reasonable.

1.3. Mechanism and operation

1.3.1. Plastic body of apparatus contains power source, oscillator impulse power electronic scheme, control unit. From control unit supply voltage comes to EHF or IR oscillator in the main body.

1.3.2. On the front panel (Fig. 2) there are:
control button of apparatus,

4 light-emitting diodes indicating switching of apparatus and action programs.

1.3.3. On the rear cover of the apparatus (Fig. 3) there is IR oscillator (IR- diode). Under the rear cover fixed by two screws, EHF generator and battery unit.

1.3.4. On the side surfaces of apparatus (Fig. 1) there is a suspension loop and fixing belt straps.

1.3.5. Apparatus is switched on by a single pressure of control button. While holding button 7 apparatus alternately passes on different action programs. At releasing the button at indication of the selected program the apparatus starts its working, oscillation is switched on. By double pressure of control button the oscillation can be switched off.

1.3.6. The apparatus is switched off automatically after expiration of time of action of the selected program in the absence of pressing the button.



Figure 1. General view
1. place for fastening the belt
2. loop

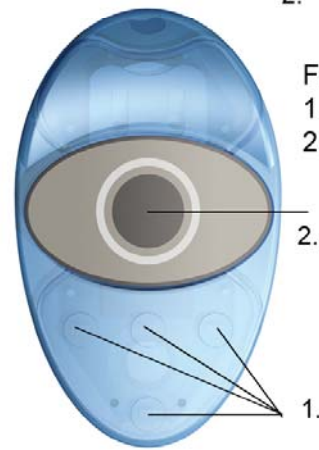


Figure 2. Front view
1. lights-indicators
2. control button

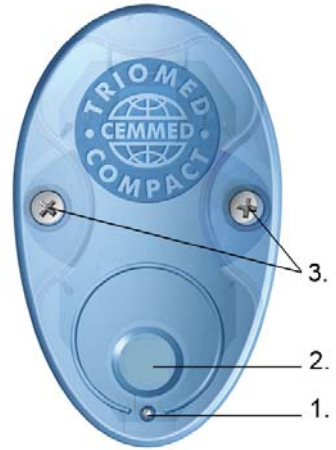


Figure 3. Rear view
1. IR oscillator
2. place of EHF generator
3. cover screws

1.4 Set

Set of the apparatus has to comply with the following indicated in table 2.

№ nn	Item	Mark	Quantity
1	IR EHF Therapy apparatus model "TRIOMED-KOMPACT 1-8"	TGKB 941.526.002	1
2	Operational documentation		
2.1	Manual	TGKB 941.526.002 RE	1
2.2	Use Instructions of the apparatus	TGKB 943.139.002 IP	1
3	Packaging	TGKB 941.526.002	1

1.5. Marking

1.5.1. Marking of the apparatus corresponds to GOST R 50444 and to set of design documentation.

1.5.2. On the inner surface of the cover there is table according to GOST 12969 which indicates:

- trade mark or producer ("OOO Triomed");

- item (EHF- IR therapy apparatus model “TRIOMED- COMPACT 1-8”);
- factory serial number;
- date of production (year, month);
- technical specifications (TU 9444-018-61005106-2010).

1.5.3. Marking is realized by method ensuring its clearness and preservation at transportation, storage and operation.

1.5.4. Marking of the package complies with GOST 14192 set of design documentation.

1.5.5. Marking of the package contains following data:

- the trade mark of producer;
- item;
- designation of the item;
- date of packaging.

Additional inscriptions characterizing the packed item and packaging are allowed.

1.5.6. Transport marking corresponds to GOST 14192 to set of design documentation.

1.5.7. Transport marking contains handling marks according to GOST R 14192: “Fragile. Handle with care”, “Beware of moisture” and inscription “Storage conditions 2”.

1.5.8. Marking is on the labels. It is allowed to mark the package directly with paint using stencil.

1.5.9. Marking has to be clear and stay during transportation and storage.

1.6. Packaging.

1.6.1. Packaging of apparatus provides protection from climatic and environment action and complies with GOST R 50444.

1.6.2. The packaging of apparatus is done in compliance with requirements of design documentation of the producer and ensures safety of apparatus at transporting and storage.

1.6.3. Apparatus is packed in the blister of thermoplastic material or in polyethylene according to GOST 10354.

1.6.4. Transport package is cardboard box.

1.6.5. Packing sheet according to GOST R 50444 is packed with each box.

1.6.6. Gross weight is not more than 10 kg.

2. FUNCTIONS

Operational restrictions, preparation of apparatus for functioning, Medical use recommendations, Operational procedure of the apparatus are described in Use Instructions TGKB 941.526.002 IP.

2.1. Safety measures

In case of failure of apparatus or emergency conditions, evacuation of medical staff special safety measures are not required.

3. TECHNICAL MAINTENANCE

3.1. Technical maintenance of apparatus (operational test and characteristics of EHF and IR oscillation) is done once per year in repair shops and after-sales service.

3.2. The operational test of apparatus is done by indication signals and order of switch on of of the light and sound devices in the process of operation.

3.3. Verification of EHF and IR radiation is done by special equipment.

3.4. Verification of EHF radiation can be done by customers independently using Indicator of electromagnetic EHF radiation "Skit" manufactured by OOO "Triomed" according to TU 6349-012-61005106-2010 and set of design documentation (KD) TGKB 435.729.002.

4. TRANSPORTATION AND STORAGE

4.1. Apparatus is transported by all transport means in accordance with the requirements of GOST R 50444 and rules of transportation of cargos valid on each type of the transport.

4.2. Conditions of transportation of apparatuses have to comply with the conditions of transportation 5 according to GOST 15150.

4.3. Conditions of storage of apparatuses in the producer's packing at the warehouses of producer and consumer have to comply with storage conditions 2 according to GOST 15150.12

5. ACCEPTANCE CERTIFICATE

IR and EHF therapy apparatus "TRIOMED" model "TRIOMED-KOMPACT 1-8"

factory serial number _____ corresponds to TU 9444-018-61005106-2010 and is recognized fit for operation.

Date of manufacturing " ____ " _____ 20__.

MP

Representative of SKK _____ (signature)

6. PACKAGING CERTIFICATE

IR and EHF therapy apparatus "TRIOMED" model "TRIOMED-KOMPACT 1-8"

factory serial number _____ is packed according to design documentation requirements.

Date of packing "___" _____ of 20__

Packed by _____.

7. WARRANTY OF PRODUCER

5.1. Producer guarantees compliance of apparatus with the requirements of technical specifications and design documentation with observation of transport, storage and operation conditions.

5.2. Warranty period of operation of the apparatus is 12 months from the day of sale.

5.3. Warranty period of storage is 6 months from the day of dispatching.

5.4. Average operating time of apparatus to the failure is not less than 1500 hours.

5.5. Average life of apparatus to disposal - not less than 5 years. After expiry of the above mentioned period of time apparatus is subject to utilization.

5.6. Use of the apparatus at the period of warranty storage ceases the action of the latter. Warranties of the producer cease after expiry of warranty period of storage.

5.7. Producer's defects at the warranty period of operation are repaired gratis on the warranty.

5.8. If during period of the warranty occur more than three warranty cases defective apparatus is subject to replacement.

5.9. Warranty is not applicable:

to faults caused by negligence or violation of rules of operation, storage and transport;

if the item was subjected to structural changes by un-authorized person;

to the item on which serial number is changed or illegible;

to the item subjected to dismantling or body opening, repair or technical maintenance in the organizations not authorized by the producer;

if damages are caused by events not depending on the producer like natural disasters, catastrophes, fires, domestic and wild animals action, insects (ants, cockroaches), objects or liquids inside the apparatus and the like;

in case of external and internal soiling, scratches, cracks, dents and other mechanical damages due to the operation or transporting;

in the absence of properly drafted guarantee coupon.

5.10. Guarantee and post-warranty repair is done by OOO "Triomed" or its authorized representatives. 5.11. If malfunction of the item does not fall to the guarantee case, repair work is carried out on the contract basis.

5.12. Information about reclamation

In case of failure of the apparatus or its malfunction in the period of action of the warranty the owner delivers or sends the apparatus by mail C.O.D. on the address of producer or enterprise ensuring after-sales service. The following documents are required to be applied to the apparatus:

Repair claim indicating address of owner and telephone numbers;

description of the defect (defective list);

guarantee coupon (Appendix A).

8. DISPOSAL

Apparatus is subject to disposal in specially designed for radio-electronic equipment container.

INFORMATION ON PRODUCER

Organization- producer: OOO "Triomed", Russia, 191036, Saint Petersburg, Ligovskiy pr. 10/118, office center hotel "October", office 5140. Telephone/fax + 7 812 578-18-47, E -mail: triomed@mail.ru

APPENDIX A

(mandatory)

Form of guarantee coupon

Enterprise OOO "Triomed", Saint Petersburg

GUARANTEE COUPON repair at warranty period

EHF IR therapy apparatus "TRIOMED"

Model "TRIOMED- COMPACT 1-8"

Number and the date of production _____ is filled up by
producer

Acquired _____ date, signature of salesman and stamp
At

Description of works

Date _____

Executed

use _____ date and signature of the owner